

1. **Banned drugs cannot be returned promptly** – The Economic Times

Chemists tell ministry that it will take them at least a month to return the drugs. Chemists and drug distributors say the government's decision last week banning hundreds of fixed dose combination drugs cannot be implemented immediately as it will take them at least a month to return the banned drugs.

The All India Organization of Chemists and Druggists, a lobby group of 750,000 wholesalers and retail chemists, said the "unpleasant action" may force its members to shut shops to return the stocks across the supply chain.

2. **Fixed- dose combos ban adds to burden of new essentials list** – The Economic Times

At least four

drugmakers have rushed to court following the ban on more than 300 fixed-dose combination (FDC) medicines, the latest and most potent of regulatory actions that has shaken up the Rs 98,000-crore Indian pharmaceutical industry. Impact of this FDC ban is estimated at around Rs 3,000 crore a year. This is in addition to the burden imposed by an enlarged essential medicines list released in December & the impending price cuts of scheduled drugs under the yearly WPI-based annual At least four drugmakers have rushed to court following the ban on more than 300 fixed-dose combination (FDC) medicines, the latest and most potent of regulatory actions

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that has shaken up the Rs 98,000-crore Indian pharmaceutical industry. Impact of this FDC ban is estimated at around Rs 3,000 crore a year. This is in addition to the burden imposed by an enlarged essential medicines list released in December & the impending price cuts of scheduled drugs under the yearly WPI-based annual price revision exercise.

3. [Govt bans Crocin Cold and Flu, D-Cold Total](#) – Business Standard

The government has banned popular cold medicines such as 'Crocin Cold and Flu' and 'D-Cold Total'. These were among the drug combinations that the government banned last week but all the names did not get disclosed at that point.

The government banned 344 drug combinations over the weekend, including codeine-based cough syrup by Pfizer and Abbott, after a government panel of experts said these had 'no therapeutic justification'.

4. [Delhi HC grants more pharma firms legal relief on combination drugs](#) – Mint

The Delhi high court on Wednesday stayed a government order banning combination drugs made by five companies—Procter and Gamble Hygiene and Health Care (P&G), Glenmark Pharmaceuticals Ltd, Reckitt Benckiser, Piramal Enterprises Ltd and Alembic Pharma Ltd.

Earlier this week, Abbott India, Macleods Pharma and Pfizer India, too, were given relief by the court.

Last week, the government banned 344 fixed-dose combination (FDC) drugs and Wednesday's order comes ahead of a decision on another 600 FDCs soon. An FDC is a cocktail of two or more active drug ingredients in a fixed ratio of doses.

5. [Ban on fixed drug combinations will shave off Rs 10,000 crore of drug industry turnover](#) – Mint

The government decision to ban 344 fixed drug combinations is irrational, says D.G. Shah, secretary general of the Indian Pharmaceutical Alliance (IPA) that represent large domestic drug makers. "Industry is not opposed to banning irrational combinations. The question is how and what evidence basis and whether you listen to the company or not," he said. Edited excerpts:

Interim relief is being given to the pharma companies but what is the big bone of contention because the government's argument is that this was done at the behest of the recommendations of an expert committee. The expert committee in its assessment has found that there is no therapeutic value to the fixed-dose combination (FDCs) that are out in the market and that there are better alternatives that are available?

What ministry of health did really for 6,220 FDCs to the expert committee. Expert committee found only 15% of that, that is 963 as irrational combinations. So, this 45% is not true. Number two, internationally India was the only pharmaceutical market where Intellectual property rights (IPR) regime was relaxed prior to Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Therefore, in an IPR regime the product patent which did not exist combining two products made a sense. And you look at this antiretrovirals. The combination which Cipla brought none of the originators were willing to do that. And that has aided the patients, the burden of pill was there 27 pills a day was reduced to 9 pills a day. Merely because international- w ally, the West does not have this doesn't mean that India cannot be an innovative country. In anti-TB, anti antiretroviral, anti malaria number of areas India is a pioneer.

6. [After health ministry bans 344 drugs, drug admin collects samples, issues notices to medical store owners](#) – The Times of India

Two days after the government prohibited the manufacture, sale and distribution of 344 fixed-dose combination (FDC) drugs with immediate effect, the Meerut drug administration (a wing of the Food Safety and Drug Administration) took as many as 12 samples of medicines from

pharmaceutical stores and issued notices to them to not use the banned medicines or face inquiry.

"We got the notification of the health ministry on Tuesday and started raiding medical stores in the city to check who all were selling the banned drugs. We have taken 12 samples from five medical stores and sent them for checking," said Sandeep Kumar, drugs inspector. The medical stores under scanner on Wednesday were Som Pharmacy, Durga Medicose, Tyagi Medicose, Deep Medicose in Khairnagar area and Santosh Medical store at Begampul.

7. [**Ban on FDC Drugs: Chemists' association approaches Kerala HC**](#) – The Times of India

All Kerala Drugists and Chemists Association (AKDCA) has approached the Kerala high court seeking more time to return over 300 medicines that were banned by the central government last week.

On March 10th, Ministry of Health and Family Welfare had issued gazette notifications - serial no. SO705(E) to SO1048(E) - banning more than 330 medicines of different manufacturers. This was based on the recommendation of an expert committee that the medicines have no therapeutic justification.

According to the notifications produced before the court, the fixed-dose combination (FDC) drugs were banned as they are "likely to involve risk to human beings whereas safer alternatives are available" and as they have "no therapeutic justification." FDC is a cocktail of two or more active drug ingredients and is preferred for their higher efficacy and lower cost. Nearly half of the drugs sold in India are estimated to be FDC.

8. [**Health experts, docs: Centres move good for patient safety**](#) – The Times of India

ven as more companies on Wednesday challenged the ban on combination drugs in the Delhi high court, public health experts and doctors have welcomed the government notification, saying withdrawal of "irrational" and "harmful" medicines from the market is good for patient safety and health. The judiciary should be cautious in granting injunctions, and scrutinise the issue with the help of clinical data before taking a decision, experts say, adding it should not be solely looked at in terms of revenue loss to companies, but also take into account public health criteria. Taking the drug industry completely by surprise, the health ministry in a notification issued late on March 12, has prohibited the manufacture, sale and distribution of nearly 336 FDCs with immediate effect. Says Leena Menghaney, a lawyer working on public health issues, "FDCs are particularly useful in the management of HIV/AIDS, malaria and tuberculosis, which are considered to be the foremost infectious disease threats today.

9. [**Just the right dose needed**](#) – Hindustan Times

The government's move to ban some fixed-dose combination drugs is long overdue and welcome. It has taken the axe so far to over 300 such combinations and is likely to move on many more. Many of these combinations have been found to be irrational, or combinations of two or more drugs in a fixed dose that bring no tangible benefit to the patient and raise the risk of doing harm. Pharmacological principles suggest that these products should exist only if the combination brings about a beneficial effect over and above that achieved by administering the products singly. Many, or most, fixed-dose combinations in India do not meet this criterion. In fact, experts say that there is a genuine raised risk of side effects and of the emergence of resistant strains of illness-causing microbes.

10. [**Drug ban explained: Most irrational combination drugs sold in India do not exist in UK or US**](#) – Firstpost

The government on Monday banned 344 fixed dose combination (FDC) drugs, including several antibiotics and analgesics, saying that a government-appointed panel of experts had found the combinations lacked "therapeutic justification". An FDC is a drug that is a combination of two or more drugs in fixed proportion. Vicks Action 500 extra is a combination of Paracetamol, Phenylephrine and Caffeine.

The problem of FDCs has been there for quite some time in the country. The companies themselves are some of those banned drugs are being sold in the country for the last 30 years. A report in The Hindu in May 2015 citing a paper published in PLOS Medicine notes that India is flooded with such risky FDCs. The paper is based on a study done in just four therapeutic areas including analgesia, anxiety/ depression and psychosis. "Most of the FDC formulations available in India [in the four therapeutic areas studied] were unavailable in either UK or the U.S," the report says quoting from the paper.

All in all, 344 is just the tip of the iceberg.

11. [India shining: PM Narendra Modi's panels of secretaries call for health, education push](#) – The Economic Times

Prime Minister Narendra Modi had set up eight Groups of Secretaries in January to suggest ways to boost growth across sectors with departmental Action Plans for "implementation in a timebound manner".

The Final Group Reports, accessed by ET, call for higher spending on health and education, better budgeting systems and major e-governance initiatives.

12. [Global patent applications from India drop to 1,423 in 2015: report](#) – Mint

Despite the government's Make in India programme, India continues to perform poorly in the "incidence and location of innovation" with international patent applications filed from the country dropping slightly to 1,423 last year—as compared to Japan's 44,235, China's 29,846 and South Korea's 14,626 in the same period.

In 2014, India filed 1,428 international patent applications as against 42,381 by Japan, 25,548 by China and 13,117 by South Korea, according to the latest figures released by the Geneva-based World Intellectual Property Organization (WIPO).

13. [Indian pharma companies are in constant touch with the US FDA: DG Shah, Indian Pharmaceutical Alliance](#) – The Economic Times

There are three major issues as far as the US FDA is concerned and companies have been working on this for the last one year. They formed a quality forum and are in constant dialogue with US FDA. The actions that needs to be taken is with regard to data reliability, culture and best practices. Changing all this and implementing in each company is a long drawn out process. But we are working constantly on a time-bound action plan with the US FDA. We are hopeful that in the next two to three , the results of the effort being put in by the major companies will start showing

14. [Health Budget Figures Tell a Sick Story](#) – The Wire

The millennium has seen some remarkable achievements in public health in India: significant declines in infant and maternal deaths, halting of the HIV/AIDS epidemic, eradication of poliomyelitis and near elimination of neonatal tetanus. What explains some of these achievements? Clearly, these were linked to increased investments in public health. Based on recommendations of the National Health Policy (2002), budget allocations to the health sector progressively increased every year from 2005: between 2005 and 2010, budgetary allocations increased by 300%, from Rs 10,000 crores to Rs 30,000 crores. From 0.9% of total GDP, public health expenditures increased to about 1.3%. Most of these increased allocations went to the National Rural Health Mission that sought architectural corrections in India's public health systems, and to especially support the lesser developed states. Not surprisingly, it is these states which made the most significant advances.

15. [High time, clear the decks for E-Pharmacy](#) - The Economic Times

The current scenario in India relating to online sale of drugs continues to remain unclear because of a circular released last year, on December 30, 2015 , by the office of the Drugs Controller General of India ("DCGI"), which directs all State and Union Territory drug controllers of India to maintain strict vigilance on online sale of drugs and take action, in public health

interest, against persons engaging in such sales in violation of the Drugs and Cosmetics Act, 1940 ("DCA") and Drugs and Cosmetics Rules, 1945 ("DCR"). However, in the said circular, while holding that the provisions under the DCR must be complied with by both brick-and-mortar sale and online sale of drugs, the DCGI admitted that no clear differentiation has been made between the two types of sales under the DCR.

16. [Govt to make pharma marketing code mandatory](#) – The Financial Express
UCPMP will help control unethical practices in the industry

Government has decided to make Uniform Code of Pharmaceutical Marketing Practice (UCPMP) mandatory in order to control unethical practices in the industry.

In a written reply to the Lok Sabha, Minister of State for Chemicals and Fertilisers Hansraj Gangaram Ahir said the government had prepared a draft UCPMP which was adopted voluntarily with effect from January 1, 2015 for six months by the pharmaceutical industry including medical device industry.

17. [Generic drug can reduce treatment cost for cancer patients](#) – Zee News

Patients suffering from chronic myeloid leukemia (CML)-- a rare form of cancer -- can get huge financial benefits if they start using the generic form of drug Gleevec, the patent of which expired in January this year, a study said.

"If we start all patients on the generic form of Gleevec and it works, then they are on a generic for the rest of their lives," said lead author William V. Padula, an assistant professor at the Johns Hopkins University. "This amounts to a huge cost savings for them and their insurers," he added.

The study, published recently in the Journal of the National Cancer Institute, said if all CML patients were started upon diagnosis on the generic form of Gleevec, known as imatinib, the cost of treatment per patient over five years would be nearly \$100,000 less than it is now.

18. [Regulators to inspect J&J's factory](#) – Business Standard

A team from the Drugs Controller General of India and Maharashtra's Food and Drug Administration (FDA) will in a day or two conduct an investigation at Johnson & Johnson's factory at Mulund in this city's northeast.

This is in the wake of the FDA's decision to send samples of J&J's Baby Powder for laboratory testing, a week after a US jury ordered the cosmetics giant to pay compensation of \$72 million to the family of a woman who won a legal battle against it. The charge was a link to ovarian cancer after decades of using the company's talc powder.

19. [USFDA issues warning letter to Emcure Pharmaceuticals](#) – The Economic Times

The US Food and Drug Administration (USFDA) has issued a warning letter to Emcure Pharmaceuticals for violating current good manufacturing practice norms at its Pune-based plant.

In the letter, the USFDA said inspectors during January 27 to February 4, 2015, had found significant deviations from standard manufacturing practices at the company's Hinjwadi, Pune-based plant.

20. [Russian delegation calls for boosting bilateral relations](#) – Business Standard

A ten-member Russian trade delegation today called for strengthening bilateral ties with India in a slew of areas, including infrastructure and pharma sector.

The delegation from Tomsk region in Russia expressed its desire to promote trade and investment ties at an interactive session organised by Confederation of Indian Industry (CII), Kerala here.

In his brief address, the head of the Russian delegation Yaroslav Tarasyuk stated that the delegation was interested in having bilateral relations with India, especially in areas such as pharma, infrastructure, nano Material, plywood, water treatment and so on.

21. [Treat in India](#) – Indian Express

A doctor friend suggested the slogan “Treat in India”. With the first meeting of the National Medical and Wellness Tourism Promotion Board (NMWTPB) held recently, I am surprised no one had thought of this expression earlier. In 2014, 7.7 million foreign tourists came to India (we don’t have full-year data for 2015). I don’t think we have a good handle on the number of tourists who come for medical purposes. The 1.3 million figure floating around is a bit of a guess and may well be an overestimate. There is a medical visa, or M-visa, issued subject to some conditions. There’s also a MX-visa, for attendants/ family members. Fast-track M/ MX visas exist for Saarc countries, although Bangladesh/ Pakistan warrant additional requirements.